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| EXAMINER | |
|---|---|
| HAYES, ROBERT CLINTON | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | |

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/357,273 | KAUFMAN ET AL. | |
| | Examiner | Art Unit | |
| | Robert C. Hayes, Ph.D. | 1647 | |

*-- The MAILING DATE of this c mmunication appears on the cover she t with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *21 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☐ Claim(s) *1-5,7 and 11-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *1-5* is/are allowed.

6)☐ Claim(s) *7 and 11-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

### *Response to Amendment*

1. The amendment filed 10/21/03 has been entered. It is noted that page 7 of the response cancels claims 6, 8-10 & 17-30. Therefore, the claim summary sheet is incorrect indicating these claims as withdrawn. Appropriate correction is required in future correspondences.

2. The oath or declaration remains defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the citizenship of each inventor.

3. The rejection of claims 3-5 & 7 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn due to the amendment of the claims.

4. The rejection of claims 14-16 under 35 U.S.C. 112, second paragraph, as being indefinite for lack of proper antecedent basis is withdrawn due to the amendment of the claims.

5. Applicant's arguments filed 10/21/03 have been fully considered but they are not deemed to be persuasive.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1-5 are allowed.

8. Claims 13-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, for the reasons made of record in Paper No: 23 (mailed 4/21/03) for claims 3-5 & 7.

The current recitation of "a host cell" encompasses a human organism. It is suggested that amending the claims to "an isolated host cell" should obviate this rejection.

9. Claims 11-12 & 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No proper antecedent basis nor conception in context with that disclosed within the specification at the time of filing Applicants' invention is apparent for the recitation of "wherein the fragment *comprises at least 10 contiguous amino acid residues* of the amino acid sequence of SEQ ID NO: 2". For example, page 9 describes *probes* of "at least 10 *nucleotides*, in which nucleotides are not amino acids, and "probes" do not encode amino acids. Note further that 10 nucleotides only encode 3 amino acids. Thus, in contrast to Applicants assertions on page 7 of

the response, no such basis exists on pages 2, 3, 9 or 19 of the specification; thereby, constituting new matter.

10. Claims 11, 12 & 16 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper No: 23 (mailed 4/21/03), and as follows.

Applicants argue on pages of the response that "there is sufficient written description in Applicants' specification regarding species homologues, fragments, and allelic variants to inform a skilled artisan that Applicants were in possession of the claimed invention at the time the application was filed, as required by section 112, first paragraph", and cites *Eli Lilly*. In contrast to Applicants' assertions, no "recitation of structural features common to the members of the genus, *which features constitute a substantial portion of the genus*" [emphasis added] is recited in the claims. In contrast, the specification solely describes the "human" DNA *species* encoding SEQ. ID NO:, versus any *genus*, in which no written description of any "lre1p" promoter sequences (i.e., as it relates to "operably linked expression control sequences" in claims 12 & 16), or any different encoded "lre1p" polypeptide variant/homologue sequence, or any different "mammalian" species of an encoded "lre1p" polypeptide, which can be structurally envisioned by one skilled in the art (i.e., by amino acid sequence) are disclosed within the specification, including what constitutes any additional sequences that merely "*comprise*" any functional fragment of SEQ ID NO:2 (versus consists of a known functional fragment of SEQ ID

NO:2), or what constitutes a single species homologues or allelic variant thereof with any distinguishable and assayable functional language (i.e., versus some unknown and undefined "biological activity"); thereby, still not meeting the written description requirements of 35 U.S.C. § 112, first paragraph, for the reasons previously made of record.

Accordingly, *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) held that "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself". *Fiddes v. Baird*, 30 USPQ2d 1481, 1483 (1993) held that claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class, in which the specification had provided an adequate description of only the bovine sequence. Similarly, only the single human DNA molecule encoding a single polypeptides species (i.e., human "lre1p" of SEQ ID NO: 2) has been described in the instant specification. Moreover, *Eli Lilly* further states in context that:

"[o]ne skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is". *Univ. California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997).

and that:

"A description of a genus of cDNAs [products] may be achieved by means of a recitation of a representative number of cDNAs [products], *defined by nucleotide sequence*, failing in the scope of the genus or of a recitation of structural features common to the members of the genus, *which features constitute a substantial portion of the genus* [emphasis added]. This is analogous to enablement of a genus under 112, [first paragraph], by showing the enablement of a

representative number of species within the genus. See Angstadt, 537 F.2d at 502-03, 190 USPQ at 218".

Therefore, in contrast, an invitation for others to discover a representative number of species with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics has not reasonably been provided within the instant specification. Thus, Applicants clearly were not reasonably in possession of the claimed genus of DNA molecules.

Applicant is again directed toward the Revised Interim Utility and Written Description Guidelines, Federal Register, Vol.64, No.244, pages 71427-71440, Tuesday December 21, 1999. For example, see Examples 7, 11, 13 & 17; and MPEP 2163.

11. Claims 11, 12 & 16 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule encoding the human hlre1p polypeptide of SEQ ID NO: 2, does not reasonably provide enablement for any structurally and functionally undefined hlre1p polynucleotides, or biologically functional equivalents thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons made of record in Paper No: 23 (mailed 4/21/03), and as follows.

In contrast to Applicants' assertions on pages 12-13 of the response, no distinguishable and assayable functional language is recited in the claims, in which the recitation "having biological activity" defines nothing; thereby, not reasonably meeting the enablement

requirements under 35 U.S.C. 112, first paragraph; consistent with the teachings of Rudinger previously made of record. It is also noted that Applicants did not address the enablement issues related to claim 16. Thus, Applicants' arguments are not persuasive, for the reasons previously made of record.

12. Claims 12 & 16 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons made of record in Paper No: 23 (mailed 4/21/03), and as follows.

It remains unclear what is exactly envisioned by the recitation of being "operatively linked to an expression control sequence", versus an expression vector comprising the polynucleotide of SEQ ID NO:1, etc., which reasonably would be operably linked to the expression *vector* control sequences, by definition. Additionally, no required vector sequences are recited in claim 11 for expressing "said polynucleotide", so that it can be subsequently "expressed", and then "isolated"; thereby, making claim 16 an incomplete method.

In contrast to Applicants' arguments on page 14 of the specification, descriptions on page 10 of the specification regarding "vectors" containing "operably-linked... expression sequence[s]" alternatively support the rejection made of record.

It is suggested that amending claim 12 to "an expression vector operably linked to the polynucleotide of claim 11", and amending claim 13 to "an isolated host transformed with the vector of claim 2 to which the polynucleotide is operably linked to vector expression sequences" should obviate this rejection.

However, note that an expression vector capable of expressing only a 10 amino acid fragment of the polynucleotide of claim 11 would not encode the polypeptide of SEQ ID NO: 2.

13. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 is dependent on now cancelled claim 6.

14. Claims 11-12 & 16 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons made of record in Paper No: 23 (mailed 4/21/03), and as follows.

It remains unclear what metes and bounds the recitation "having biological activity" is envisioned to entail, in that no specific assayable activity is recited in the claims. In other words, an open ended definition of an undefined "biological activity" defines nothing.

It is suggested that amending the claims to "having autophosphorylation and endoribonucleease activity" should obviate this particular rejection

15. Claims 11-12 & 16 stand rejected under 35 U.S.C. 102(b) as being anticipated by Mori et al. (IDS ref # C4; 1993), for the reasons made of record in Paper No: 23 (mailed 4/21/03), and as follows.

Applicants argue on page 16 of the response that they have amended the claims to obviate the rejection. In contrast to Applicants' assertions, amending only the recitation of what

constitutes a fragment in the Markush group of claim 11 does not obviate the other limitations recited in the Markush group of claim 11. Thus, Applicants' arguments are moot.

It is noted that the amended claims no longer anticipate claim 11c, even though this particular rejection may be re-instated if Applicants amend the claims to overcome the new matter rejection above.

In summary, Mori et al. teach a polynucleotide encoding an IRE1 protein "comprising a fragment of the amino acid sequence of SEQ ID NO:2" (i.e., residue #s 622-628; pg. 747; Fig. 4), which inherently has immunogenic "biological activity", etc. In that Mori's IRE1 polynucleotide meets the loosely defined limitations of both an "allelic variant" and "species homologue" of the polynucleotide of SEQ ID NO:1 (e.g., as defined on page 10 of the specification), claim 11d-e is also anticipated. In that Mori teach expression vectors/control sequences (e.g.., pSEYc102, pERN1EM, pMAL-c2, etc.), yeast and/or *E. coli* host cells, and a method of recombinantly producing their IRE1 polypeptide (e.g., pgs. 753-754), the limitations of claims 12 & 16 are also anticipated.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert C. Hayes, Ph.D.
January 12, 2003

GARY KUNZ
SUPERVISORY PATENT EXAMINER
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